K121106

APR 27 2012

510(k) Summary

807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	Surgical Appliance Industries, Inc.
Company Address	3960 Rosslyn Drive Cincinnati, Ohio 45209-1195
Telephone:	800-888-0458
Fax:	800-309-9055
Contact Person:	Gary Parsons

Summary Preparation Date: December 13, 2011

DEVICE NAME **807.92(a)(2)**

Trade Name:	TRUFORM® Ready-To-Wear Compression Arm Sleeve TRUFORM® Ready-To-Wear Compression Gauntlet
Common/Usual Name:	Compression Garment
Classification Name:	Stocking, Medical Support (To Prevent Pooling Of Blood In Legs)
Regulation Number:	880.5780
Product Code:	DWL
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

510k #	***Product***	***Manufacturer***
K013852	Jobst Ready-To-Wear Gauntlet	BSN-Jobst, Inc.
K991570	Jobst Ready-To-Wear Sleeve	BSN-Jobst, Inc.

DEVICE DESCRIPTION **807.92(a)(4)**

The TRUFORM® Ready-To-Wear Compression Arm Sleeve is circular knit with nylon and spandex yarns, is available in 3 sizes – small, medium, and large, and is latex free, air-permeable and available in beige, black and brown.

The sizing of the TRUFORM® Ready-To-Wear Compression Arm Sleeve is based on circumferential measurements taken around the smallest part of the wrist, mid-lower arm, and around the mid-upper arm and is limited to individuals that fall within those specified ranges.

The TRUFORM® Ready-To-Wear Compression Gauntlet is circular knit with nylon and spandex yarns, is available in 3 sizes – small with compression of 15- 20 mmHg, medium with

compression of 20-30 mmHg and large with compression of 20-30 mmHg. The thumb piece is sewn in place during a second operation. The TRUFORM® Ready-To-Wear Compression Gauntlet is latex free, air-permeable and available in beige, black and brown.

The sizing of the TRUFORM® Ready-To-Wear Compression Gauntlet is based on circumferential measurements taken around the palm and around the smallest part of the wrist, and is limited to individuals that fall within those specified ranges in sizing chart.

DEVICE INTENDED USE **807.92(a)(5)**

The TRUFORM® Ready-To-Wear Compression Arm Sleeve is intended to be used to apply pressure to the upper extremity and is indicated for use in the management of mild to moderate Lymphedema and other edema, phlebitis, post-thrombotic syndrome and vascular malformations.

The TRUFORM® Ready-To-Wear Compression Gauntlet is intended to be used to apply pressure to the hand and wrist and is indicated for use in the management of Lymphedema and other edema.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

The TRUFORM® Ready-To-Wear Compression Arm Sleeve and TRUFORM® Ready-To-Wear Compression Gauntlet are similar to the predicate devices in material used, mode of action and indications for use and can be considered as safe and effective as the predicate products.

NONCLINICAL TEST **807.92(b)**

SAFETY and EFFECTIVENESS

Comparative compression bench test

A comparative compression bench test was conducted to determine the substantial equivalence of the TRUFORM® Ready-To-Wear Arm Sleeve compared to the Jobst Ready-To-Wear Arm Sleeve (K991570). Comparative testing reveals that Jobst predicate sleeves and TRUFORM® sleeves are substantially equivalent in measuring mmHg of compression.

A comparative compression bench test was conducted to determine the substantial equivalence of the TRUFORM® Ready-To-Wear Gauntlet compared to the Jobst Ready-To-Wear Gauntlet (K013852). Comparative testing reveals that Jobst predicate gauntlets and TRUFORM® gauntlets are substantially equivalent in measuring mmHg of compression.

Usability and Label Comprehension Study

User studies conducted for usability and label comprehension showed that the over the counter purchaser of this device could read and understand the instructions, and could properly use the device.

The results demonstrated that 100% of the responses to the questions were strongly agree or agree.

CONCLUSION **807.92(b)(3)**

The TRUFORM® Ready-To-Wear Compression Gauntlet and TRUFORM® Arm Sleeve are substantially equivalent to the predicate device in:

- Intended Use
- Material Characteristics and
- Performance Characteristics

After analyzing comparative compression bench test and user testing data, it is the conclusion of Surgical Appliance Industries that the TRUFORM® Ready-To-Wear Compression Arm Sleeve and TRUFORM® Ready-To-Wear Compression Gauntlet are as safe and effective as the predicate device. User studies showed that the over the counter purchaser of this device could read and understand the instructions and could properly use the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Surgical Appliance Industries, Incorporated
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

APR 2 7 2012

Re: K121106
Trade/Device Name: TruForm® Ready-To-Wear Arm Sleeve and Gauntlet
Regulation Number: 21 CFR 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: April 11, 2012
Received: April 12, 2012

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K121106

Device Name: TruForm® Ready-To-Wear Arm Sleeve and Gauntlet

Indications for Use:

The TRUFORM® Ready-To-Wear Compression Arm Sleeve is intended to be used to apply pressure to the upper extremity and is indicated for use in the management of mild to moderate Lymphedema and other edema, phlebitis, post-thrombotic syndrome and vascular malformations.

The TRUFORM® Ready-To-Wear Compression Gauntlet is intended to be used to apply pressure to the hand and wrist and is indicated for use in the management of Lymphedema and other edema.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___V___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

4/27/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121106